repetitive" and that "[i]t is unclear [what] the purpose of the repetition of this recitation" is.

It is respectfully pointed out to the Examiner that the amendments to claim 1 and 12 removes the basis for this rejection.

Item # 6-B1. The Examiner states that "[c]laim 26 is indefinite" because of an inadvertently added step.

It is respectfully pointed out to the Examiner that the amendment to claim 26 removes the basis for this rejection.

Item # 6-C1. The Examiner states that "[c]laim 54 is indefinite because the claims do not recite a positive process step which clearly relates back to the preamble."

It is respectfully pointed out to the Examiner that the amendment to claim 54 removes the basis for this rejection. The term "analyze" is adequate described in the specification (See pages 8-9).

35 USC 103

Item # 7. The Examiner states that "[c]laims 1-3, 5-6, 11-21, 23-30, 32-33, 37,39, 41, 45-51, 53-56, 58, 60-62 are rejected under 35 USC 103(a) as being unpatentable over Boom et al (5,234,809) in view of Shieh (US Pat. 6,054,039, April 2000)."

It is respectfully pointed out to the Examiner that Boom teaches an invention in which the lysing reagent (a chaotropic substance) is added in excess to a vessel containing the

solid support (silica beads) such that the biological material and solid support form a particulate suspension in the lysing reagent. As described in col. 4, lines 5-9, Boom teaches a method in which the "starting material is mixed with sufficiently large amounts of chaotropic substance for instance guanidinium salt and for instance silica particles to release all of the nucleic acid present in the starting material and bind it to said silica particles." Boom states that a suitable protocol is one in which a suspension of silica particles are attached to a buffered GuSCN solution in a reaction vessel, to which the sample is added and thoroughly mixed (See col. 4, lines 9-12). However, as the Examiner has correctly noted, Boom does not teach a method in which the lysing reagent is first bound, and unbound lysing reagent is removed prior to the contacting of the biological treatment. Additionally, the crucial DNA releasing step in Boom is contacting the cells with the chaotropic substance in suspension. Boom does not suggest that passing cells over a matrix to which a mild lysing reagent is bound will result in lysis and the release of DNA.

However, the Examiner incorrectly assumes that it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Boom, with the method and pre-treatment method of Shieh. Shieh merely teaches the separation of red blood cells from whole blood and their lysis thereafter. In the method of Shieh, a membrane having a pore size sufficient to retain red blood cells while allowing the liquid fraction of whole blood to pass through is used. The method of the present invention does not preferentially filter out blood components like the method disclosed in Shieh does, nor does it separate out certain cell types over other cell types. Thus, the references together do not teach nor suggest the process disclosed in the present invention.

Item # 8. The Examiner states that "[c]laims 1-3, 5-6, 11-21, 23-30, 32-33, 37,39, 41, 45-51, 53-56, 58, 60-62 are rejected under 35 USC 103(a) as being unpatentable over Boom et al (5,234,809) in view of Rupar et al (US Pat. 6,093,695, July 2000)."

It is respectfully pointed out to the Examiner that Rupar does not teach contacting a biological material with a lysing matrix. In Rupar, the bacterial cells are grown on one side of a filter which is subsequently soaked in a high salt solution to lyse such cells. It would be inconceivable to combine the invention of Boom with Rupar to yield the present invention.

Item # 9. The Examiner states that "[c]laims 1-20, 24-33, 37-41, 44-49, 54-62 are rejected under 35 USC 103(a) as being unpatentable over Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000)."

The Examiner claims that "Deggerdal teaches in the specification that the 'nucleic-acid containing sample may be contacted with the detergent and solid phase which may be added to the sample prior to, simultaneously with, or subsequently to the detergent . . . " Thus, the Examiner concludes that "Deggerdal is inherently teaching a solid support to which a lysing reagent is 'bound' with the recitation that the sample may be added subsequently to the detergent."

It is respectfully pointed out to the Examiner that Deggerdal teaches a method which comprises simultaneous steps of adding the solid support (Dynabeads) to the lysing reagent to form a suspension in which the lysing reagent is present in excess. The instant invention, on the other hand, recites the use of a solid support to which the lysing reagent is bound and any

excess lysing reagent removed. The instant invention also teaches the use of a solid support to which a lysing reagent is bound and dried before applying the biological material to be lysed. Thus, the instant invention is not the invention of Deggerdal. Shieh merely teaches the separation of red blood cells from whole blood and their lysis thereafter. Thus, the references together do not teach nor suggest the method of the invention.

Item # 10. The Examiner states that "[c]laims 1-20, 24-33, 37-41, 44-49, 54-62 are rejected under 35 USC 103(a) as being unpatentable over Deggerdal (WO 96/18731) in view of Rupar et al (US Pat. 6,093,695, July 2000)."

The aforementioned discussions detailing the differences between the current invention and the inventions of Deggerdal and Rupar overcome this rejection cited by the Examiner.

Item # 11. The Examiner states that "[c]laims 38 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,234,809) in view of Shieh (US Pat. 6,054,039, April 200) or Rupar (US Pat. 6,093,695, July 2000) as applied to Claims 1-3, 5-6, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, 53-56, 58, 60-62 above, and further in view of view of Deggerdal (WO 96/18731)."

The aforementioned discussions detailing the differences between the current invention and the inventions of Deggerdal, Rupar and Shieh overcome this rejection cited by the Examiner.

Item # 12. The Examiner states that "[c]laims 23 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal (WO 96/18731) in view of Shieh (US Pat.

6,054,039, April 2000) or Rupar (US Pat. 6,093,695, July 2000) as applied to Claims 1-20, 24-33, 37-41, 44-49, 54-62 above and further in view of Boom (5,234,809).

The aforementioned discussions detailing the differences between the current invention and the inventions of Deggerdal, Rupar and Shieh overcome this rejection cited by the Examiner.

Item # 13. The Examiner states that "[c]]laims 7, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,234,809) in view of Shieh (US Pat. 6,054,039, April 2000) or Rupar (US Pat. 6,093,695, July 2000) as applied in Claims 1-3, 5-6, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, 53-56, 58, 60-62 above and further in view of Su (5,804,684).

The aforementioned discussions detailing the differences between the current invention and the inventions of Boom, Rupar and Shieh overcome this rejection cited by the Examiner.

Item # 14. The Examiner states that "[c]laims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,804,684) in view of Shieh (US Pat. 6,054,039, April 2000) or Rupar (US Pat. 6,093,695, July 2000) as applied to Claims 1-3, 5-6, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, 53-56, 58, 60-62 above or Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) or Rupar (US Pat. 6,093,695, July 2000) as applied to Claims 1-20, 24-33, 37-41, 44-49, 54-62 above and further in view of Su (5,804684).

#15 "[C]laims 22 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,804,684) in view of Shieh (US Pat. 6,054,039, April 2000) or Rupar (US Pat. 6,093,695, July 2000) as applied to Claims 1-3, -5-6, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, 53-56, 58, 60-62 above or Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039,

April 2000) or Rupar (US Pat. 6,093,695, July 2000) as applied to Claims 1-20, 24-33, 37-41, 44-49, 54-62 above and further in view of Sambrook (Molecular Cloning).

Item # 16. The Examiner states that "[c]laims 33 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,804,684) in view of Shieh (US Pat. 6,054,039, April 2000) or Rupar (US Pat. 6,093,695, July 2000) as applied to Claims 1-3, 5-6, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, 53-56, 58, 60-62 above or Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) or Rupar (US Pat. 6,093,695, July 2000) as applied to Claims 1-20, 24-33, 37-41, 44-49, 54-62 above and further in view of Arnold (5,599,667).

The aforementioned discussions detailing the differences between the current invention and the inventions of Deggerdal, Rupar and Shieh overcome this rejection cited by the Examiner.

Item # 17. The Examiner states that "[c]laim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,804,684) in view of Shieh (US Pat. 6,054,039, April 2000) or Rupar (US Pat. 6,093,695, July 2000) or Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) or Rupar (US Pat. 6,093,695, July 2000) or Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) or Rupar (US Pat. 6,093,695, July 2000) and further in view of Arnold (5,599,6667) as applied to claim 33, 35-36 above, and further in view of Hasebe (5,151,345).

The aforementioned discussions detailing the differences between the current invention and the inventions of Deggerdal, Rupar and Shieh overcome this rejection cited by the Examiner.

Based on the amendments and remarks above, applicants believe that all pending claims are in condition for allowance.

If the Examiner believes that a conference would be of value in expediting the prosecution of this application, the Examiner is hereby invited to telephone undersigned counsel to arrange for such a conference.

Respectfully submitted,

Dated: May 22, 2001

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Appendix A

1. A process for characterizing DNA comprising a step of isolating nucleic acids, wherein the step of isolating comprises the steps of:

(a) contacting a biological material that contains DNA with a solid support treated with a lysing reagent wherein the solid support has not contacted the biological material at the time of treatment;

(b) treating the biological material that contains DNA with a DNA purifying reagent;

(c) purifying the DNA from the remainder of the biological material[,]

[wherein the lysing reagent is bound to the solid support]; and

(e) analyzing the purified DNA,

wherein the lysing reagent is bound to the solid support and any unbound lysing reagent is removed from the solid support before the biological material is contacted with the solid support.

26. A process for amplifying DNA sequences, wherein the process comprises the steps of:

(a) contacting a biological material that contains DNA with a solid support treated with a lysing reagent wherein the solid support has not contacted the biological material at the time of treatment;

(b) treating the biological material with a DNA purifying reagent;

(c) purifying the DNA; and

applying the purified DNA to an amplification system, wherein the lysing reagent is bound to the solid support and any unbound lysing reagent is removed from the solid support before the biological material is contacted with the solid support.

[(Twice Amended) The process of claims 26 and 27, wherein the solid support is contained in a vessel, wherein the vessel is selected from [a] the group consisting of centrifuge tubes, spin tubes, syringes, cartridges, chambers, multiple-well plates, test tubes, and combinations thereof.]

28. The process of claims 26 or 27, wherein the solid support is contained in a vessel, wherein the vessel is selected from [a] the group consisting of centrifuge tubes, spin tubes, syringes, cartridges, chambers, multiple-well plates, test tubes, and combinations thereof.

33. The process of claims 26 or 27, wherein the solid support is selected from [a] the group consisting of cellulose, cellulose acetate, glass fiber, nitrocellulose, nylon, polyester, polyethersulfone, polyolefin, polyvinylidene fluoride, and combinations thereof.

54. A process for characterizing DNA comprising a step of isolating nucleic acids, wherein the step of isolating comprises the steps of:

(a) contacting a biological material that contains DNA with a solid support treated with a lysing reagent wherein the solid support has not contacted the biological material at the time of treatment;

(b) treating the biological material that contains DNA with a DNA purifying reagent;

(c) purifying the DNA from the remainder of the biological material;

(d) and analyzing the purified DNA;

wherein the lysing reagent is bound to the solid support; wherein the lysing reagent is bound to the solid support and dried to the solid support.